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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,903	LEBRUN, STEWART J.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/17/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment, received October 17, 2003 is acknowledged. Specification page 1 has been amended to include a priority statement to a provisional application.

2. Applicant's Information Disclosure Statement, received October 17, 2003 is acknowledged. The foreign references, which did not include a translated copy, are not initialed by the examiner and have not been considered (See attached PTO form 1449).

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 are, drawn to a method for detecting a disease and presence of an antigen, classified in class 435, subclass 69.3.

II. Claim 3 is, drawn to a method for monitoring protein degradation, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II are drawn to distinct methods. Each of the methods are distinct each from the other because the have different goals (as evidenced by their different preambles), have different method steps, utilize different reagents and have different final outcomes. For example, the method of group I, involves detection of disease or autoimmune state in a mammal, antigens and antibodies. The method of group II only involves a metal-protein conjugate but no antigens or antibodies or diagnosis of a disease in a mammal.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. The inventions of groups I and II have a separate status in the art as shown by their separate classification. In the instant case, the searches of group I and II are not coextensive. Group I encompasses methods of detecting disease using antigens and antibodies. In contrast group II would require a text search for a method for monitoring protein degradation using a metal-protein conjugate.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Mark Benedict (reg# 44531) on 10/20/2004 a provisional election was made without traverse to prosecute the invention of I, claims 1-2. Affirmation of this election must be made by applicant in replying to this Office action. Claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The disclosure is objected to because of the following informalities:

The use of the trademark ζ-Grip has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Specification page 5, paragraph 0019 the abbreviation PDVF is used, the full

name or explanation of the above abbreviations are required when appear in the specification for the first time.

Specification page 8, paragraph 0026 the abbreviations SSA/RO, SLE and BNCIP are used, the full name or explanation of the above abbreviations are required when appear in the specification for the first time.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detection of SSA/RO antigens from SLE patients serum, does not reasonably provide enablement for all disease or autoimmune antigens in all mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working

examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claims are broadly drawn to a method of detecting disease or autoimmune state in a mammal. The specification is only enabled for an immunogenic test detecting SSA/Ro antigen in the serum of SLE patients (see page 9). The specification describes preparation of metal antibody conjugate (see page 9).

With regard to factors five and eight, it is noted that the working examples are limited to the given examples in the specification in pages 9-10 describe preparation of of metal antibody conjugate and testing of patients serum for SSA/Ro antigen. Such seen as insufficient to support the breath of the claims, wherein the scope of the claims encompasses detecting any disease known now or be discovered or autoimmune state in a mammal. In the instant case claim 1 is drawn to a method of detecting disease. In regard to factors two and three it is well known in the art that detection and diagnosis of diseases are very broad. The mammals suffer from a variety of disease, which differ in their source and cause. However, there is unpredictability in the art for the scope of the instant claims, i.e. detecting any/all disease, autoimmune state and/or antigen(s) by the claimed method. Disease in mammals are multifaceted wherein an antigen activity may/may not be involved in the manifestation of disease. The art teaches that current definitions of infectious diseases can be somewhat vague and depends on culturing the organism, detecting antigens from the organism, detecting IgM antibodies to the organisms or detecting an increase in the antibody titer after acute phase of the infection. Much has been accomplished, but much remains to be

discovered, defined and developed for efficient diagnosis of infectious disease (see Immunoserology of Infectious diseases, review article by Karen James, Clinical Microbiology Reviews, Vol. 3, No.2, April 1990). William Egner in his article in the Journal of Clinical Pathology, vol. 53, 2000 teaches that autoantibodies are usually polyclonal of mixed isotype affinity, and avidity and are often directed against multiple targets. Different assays detect particular antibody properties, which are quite often different. Therefore, detection of autoimmune state in a mammal is very complicated.

Thus, applicant have **not** provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed method in manner reasonably correlated with the scope of the claims broadly detecting any disease or autoimmune state. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes, which can be made in the method, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the invention commensurate in scope with the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3 recites the statement of " immobilizing a disease or autoimmune antigen on a substrate", it is unclear what is being immobilized.

Claim 1, lines 11 and 12 recite, " wherein conduction of a current is indicative of disease or autoimmune state", it is not clear how conduction of a current indicate a disease.

Claim 2, line 3 recite " under conditions such" , it is not clear what these conditions are.

Claim 2, lines 10 and 11 recite, " wherein conduction of a current is indicative of the presence of said antigen" it is not clear how conduction of a current indicate presence of an antigen.

Claims 1-2 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: There is no washing or rinsing step after the reaction of antigen and antibody conjugate.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645
March 14, 2005

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER